

a cavity disposed between its proximal and distal ends. A resilient member is provided is disposed in that cavity. A clamp is provided that can be moved from an open position, in which the resilient member is unaffected, and a clamp position, in which strain on the resilient member reduces the inner diameter of the opening through the resilient member. Claim 10 further recites a spinal needle, freely axially moveable within the hollow bore of the tube, that is fixed with respect to the epidural needle when the inner diameter of the resilient member is reduced.

In contrast, the '953 patent is related to a sheath introducer with a valve that splits. Specifically, the '953 patent discloses a sheath 10 that terminates at a support tube 20. A tab 24 is carried on the support tube. As can be seen by reference to Figs. 3 and 4 of the '953 patent, valve assemblies 80 and 80a are moved from a closed condition to an open condition by separating co-mating surfaces 84 and 84a. There is no disclosure of a resilient member that is strained to reduce its inner diameter or, in fact, any member placed between the co-mating surfaces. While the Examiner has stated that the proximal end 12 of the sheath is a resilient member, there is no teaching in the '953 patent that the sheath is resilient, or that it is strained to reduced its inner diameter. Indeed, the co-mating surfaces do not operate on the sheath at all, let alone in the manner set forth in the claims. Rather, the co-mating surfaces come together directly to prevent fluid flow through the tab. Even if there were a suggestion to modify the '953 patent to include a resilient member (and there is not), it is not clear where and how such a resilient member could be incorporated into the structure of the '953 patent. Indeed, such a construction would not be operable since the joining of the co-mating surfaces (which effects a seal in the '953 patent) would be interrupted by such a resilient member. Consequently, claims

1 and 10, as well as the claims that depend therefrom, are believed patentable over the '953 patent.

Regarding claims 3 and 12, the handle 90 of the '953 patent does not serve as a releasable latch as set forth in these claims. The latch permits the caregiver to selectively place the clamp in a clamped position or in an open position – and the latch will maintain that condition. In contrast, the handle 90 of the '953 patent merely permits the caregiver to overcome the bias of the spring in the tab, allowing for fluid flow. Upon release of the handle, the valve automatically returns to a closed condition.

Regarding claims 4, 5, 13 and 14, the '953 patent does not disclose a releasable latch and therefore cannot meet the elements of this claim. In any case, it is unclear what structure serves as a push tab on the handle 90 (which has been identified as a latch by the Examiner). Clarification is respectfully requested.

Regarding claims 6-9 and 15-18, the Examiner has merely stated that these structures are depicted in Fig. 3 of the '953 patent. It is unclear what structures the Examiner is relying on to serve as the claimed support legs and their radiused portions. Clarification is respectfully requested.

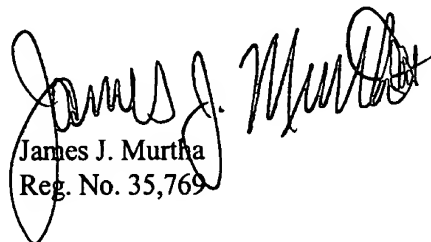
Regarding claim 10, the Examiner has stated that the '953 patent discloses an epidural needle (numeral 10). Applicant's attorney respectfully notes that numeral 10 refers to the sheath. There is no disclosure that the sheath is part of an epidural needle. Further, the Examiner states that a spinal needle is disclosed in the '953 patent at col. 3, lines 23. There is no teaching or suggestion that the "lead" referred to in this section is a spinal needle. Further, there is no suggestion of the combination of elements set forth in claim 10.

New claim 19 is directed to a needle including an elongate tube, a hub, a resilient member disposed in the hub and a clamp for selectively deforming the resilient member to change its inner diameter. As discussed above, these features are not taught or suggested by the '953 patent. Further, new claim 20 includes a clamp made of a U-shaped member with a latch used to lock the legs of the U-shaped member in a fixed position. Again, this structure is neither taught nor suggested by the '953 patent. Consequently, these claims are believed patentable over the '953 patent.

#### Conclusion

The claims of the instant application are believed patentable over the art of record and prompt, favorable action is respectfully requested. Should any issues remain outstanding, the Examiner is invited to call the undersigned.

Respectfully submitted,

  
James J. Murtha  
Reg. No. 35,769

Becton, Dickinson and Company  
1 Becton Drive  
Franklin Lakes, New Jersey 07417-1880  
(201) 847-7160

**VERSION WITH MARKINGS TO SHOW CHANGES MADE**

19. A needle including:

an elongate tube defining a longitudinal axis having a proximal end, a distal end and an axial bore having an inside diameter therethrough;

a hub having a proximal end, a distal end and an open passageway therethrough, the hub being attached to the elongate tube so that the hollow bore of the elongate tube is in fluid communication and substantial axial alignment with the open passageway, the hub further having a cavity disposed therein between the proximal end and the distal end of the hub;

a resilient member, distinct from the elongate tube, having an opening therethrough defining an inner diameter and disposed in the cavity so that the opening is substantially aligned and in fluid communication with the open passageway; and

a clamp selectively moveable between a first position wherein the resilient member is undeformed and a second position wherein the resilient member is deformed such that the inner diameter of the opening is changed through at least a portion of the resilient member.

20. The needle of claim 19 wherein the clamp comprises a deformable U-shaped member having an apex and two legs, wherein a living hinge is disposed at the apex and a latch is disposed on the legs for securing the legs in a relatively fixed position.